IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

VANDERBILT UNIVERSITY MEDICAL CENTER,)		
Plaintiff,)		
vs.)	No	
T2 BIOSYSTEMS, INC.)		
Defendant.)		

COMPLAINT FOR BREACH OF CONTRACT

COMES NOW, Plaintiff, Vanderbilt University Medical Center ("VUMC"), by and through counsel, and for its Complaint against Defendant T2 Biosystems, Inc. ("T2 Biosystems"), states as follows:

PARTIES AND JURISDICTION

- 1. Plaintiff, VUMC, is a Tennessee not-for-profit corporation, duly authorized to conduct business in the State of Tennessee with its principal place of business located at 1161 21st Avenue South, Medical Center North D-3300, Nashville, Tennessee 37232.
 - 2. VUMC is a citizen of the State of Tennessee.
- 3. Defendant, T2 Biosystems, is a Delaware corporation, with its principal place of business located at 101 Hartwell Avenue, Lexington, Massachusetts 02421, and is registered to do business in the State of Tennessee as a foreign corporation.
 - 4. T2 Biosystems is a citizen of the State of Delaware and the State of Massachusetts.
- 5. T2 Biosystems may be served through its registered agent, Corporation Service Company, 2908 Poston Avenue, Nashville, Tennessee 37203.

- 6. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because there is complete diversity of citizenship between VUMC and T2 Biosystems, and the amount in controversy alleged by VUMC exceeds the sum or value of \$75,000.00, exclusive of interest and costs.
- 7. This Court has personal jurisdiction over T2 Biosystems because it directed its commercial activities into Tennessee. It chose VUMC to conduct a clinical trial. It knew the clinical trial would be conducted in Tennessee and it directed communications and payments into Tennessee during the course and scope of the relationship with VUMC.
- 8. Venue is proper under 28 U.S.C. § 1391(b) because a substantial part of the events giving rise to this action occurred in this District and relate to a clinical trial study conducted within this District.

FACTS APPLICABLE TO ALL COUNTS

- 9. Headquartered in Nashville, Tennessee, VUMC is one of the largest and most prominent academic systems in the Southeast, providing patient care, conducting research, and training the next generation of health professionals.
 - 10. T2 is a company in the business of developing medical diagnostic products.
- 11. On June 8, 2023, T2 Biosystems entered into an Investigator-Initiated Accelerated Clinical Trial Agreement with VUMC (the "Agreement") to engage VUMC to act as a site to conduct a clinical trial titled "Effect of direct-from-blood bacterial testing on antibiotic administration and clinical outcomes: A learning healthcare randomized clinical trial" (the "Study"). A true and correct copy of the Agreement is attached as **Exhibit 1**.

- 12. Pursuant to the express terms of the Agreement, VUMC agreed to conduct the Study as set forth in the Protocol attached as Exhibit A to the Agreement. *See* Protocol, attached as Exhibit A to Ex. 1.
- 13. Pursuant to the express terms of the Agreement, T2 Biosystems agreed to compensate VUMC under a milestone-based schedule for the performance of Study activities within forty-five (45) days from the date of the invoice as set forth in the Budget attached as Exhibit C to the Agreement. *See* Budget, attached as Exhibit C to Ex. 1.
- 14. For illustrative purposes, an excerpt of the Budget's seven milestones and corresponding disbursement amounts in Exhibit C to the Agreement is included below:

Milestone	Disbursement Number	Disburs	ement Amount
Contract Executed	1	\$	25,000.00
IRB Approved	2	\$	25,000.00
First Patient Enrolled	3	\$	50,000.00
50% of Sample Size Enrolled	4	\$	100,000.00
Enrollment Complete	5	\$	100,000.00
Analysis of Primary and Secondary Outcomes Complete	6	\$	48,675.00
Manuscript Submitted for Publication	7	\$	48,675.00
	Total		\$397,350.00

- 15. VUMC has completed Milestones One through Five.
- 16. In accordance with the terms of the Agreement, VUMC submitted invoices for each completed milestone, which were due within "forty-five (45) days from the date of the invoice." *See* Budget, attached as Exhibit C to Ex. 1.
- 17. On June 8, 2023, VUMC completed the contract execution of the Study ("Milestone One").

- 18. VUMC submitted Invoice No. GR015647-202307-001, dated July 6, 2023, in the total amount of \$25,000.00, which reflected the completion of Milestone One (the "Milestone One Invoice"). A true and correct copy of the Milestone One Invoice is attached as **Exhibit 2**.
 - 19. T2 Biosystems paid, in full, the Milestone One Invoice on or about August 5, 2023.
- 20. On or about September 29, 2023, VUMC completed the IRB approval of the Study ("Milestone Two").
- 21. VUMC submitted Invoice No. GR015647-202309-002, dated September 29, 2023, in the total amount of \$25,000.00, which reflected the completion of Milestone Two (the "Milestone Two Invoice"). A true and correct copy of the Milestone Two Invoice is attached as **Exhibit 3.**
- 22. T2 Biosystems paid, in full, the Milestone Two Invoice on or about October 29, 2023.
- 23. On or about December 14, 2023, VUMC completed enrollment of the first patient of the Study ("Milestone Three").
- 24. VUMC submitted Invoice No. GR015647-202312-003, dated December 14, 2023, in the total amount of \$50,000.00, which reflected the completion of Milestone Three (the "Milestone Three Invoice"). A true and correct copy of the Milestone Three Invoice is attached as

Exhibit 4.

- 25. T2 Biosystems paid, in full, the Milestone Three Invoice on or about January 13, 2024.
- 26. On or about July 8, 2024, VUMC completed the enrollment of fifty percent (50%) of the sample size of the Study ("Milestone Four").

- 27. VUMC submitted Invoice No. GR015647-202407-004, dated July 9, 2024, in the total amount of \$100,000.00, which reflected the completion of Milestone Four (the "Milestone Four Invoice"). A true and correct copy of the Milestone Four Invoice is attached as **Exhibit 5**.
- 28. On or about July 30, 2024, T2 Biosystems paid only \$25,000.00 of the total \$100,000.00 owed on the Milestone Four Invoice, leaving \$75,000.00 outstanding.
- 29. Pursuant to the express terms of the Agreement, T2 Biosystems should have paid the Milestone Four Invoice, in full, no later than August 23, 2024. *See* Budget, attached as Exhibit C to Ex. 1; *see also* Ex. 5.
- 30. To date, T2 Biosystems has failed to pay the remaining \$75,000.00 balance of the Milestone Four Invoice.
- 31. On or about December 6, 2024, VUMC completed enrollment of the Study ("Milestone Five").
- 32. VUMC submitted Invoice No. GR015647-202412-005, dated December 10, 2024, in the total amount of \$100,00.00, which reflected the completion of Milestone Five (the "Milestone Five Invoice"). A true and correct copy of the Milestone Five Invoice is attached as
- 33. Pursuant to the express terms of the Agreement, T2 Biosystems should have paid the Milestone Five Invoice, in full, no later than January 24, 2025. *See* Budget, attached as Exhibit C to Ex. 1; *see also* Ex. 6.
 - 34. To date, T2 Biosystems has failed to pay the Milestone Five Invoice.

Exhibit 6.

35. Despite VUMC's compliance with its obligations under the Agreement, and repeated efforts by VUMC to collect payment on the Milestone Four Invoice and the Milestone

Five Invoice, and despite T2 Biosystems' repeated assurance that it intended to pay, T2 Biosystems has refused to pay VUMC the \$175,000.00 owed.

CAUSES OF ACTION

COUNT ONE - BREACH OF CONTRACT

- 36. VUMC reaffirms and realleges the forgoing paragraphs as if set forth fully herein.
- 37. The Agreement constitutes a valid and binding contract between VUMC and T2 Biosystems.
- 38. VUMC agreed to conduct the Study in accordance with the Protocol, and T2 Biosystems agreed to compensate VUMC for its performance of the work on the Study in accordance with the Budget.
- 39. VUMC fully complied with its obligations under the Protocol of the Agreement and has completed Milestones One through Five.
- 40. T2 Biosystems has breached its obligations under the Agreement by failing to pay the remaining \$75,000.00 balance on the Milestone Four Invoice by August 23, 2024.
- 41. T2 Biosystems has breached its obligations under the Agreement by failing to pay the Milestone Five Invoice by January 24, 2025.
- 42. T2 Biosystems owes VUMC the total amount of \$175,000.00 for the completion of Milestone Four and Milestone Five but has not paid VUMC for the performance of the Study activities.
- 43. VUMC has incurred damages as a direct and proximate cause of T2 Biosystems' breach of the Agreement and is entitled to recover those damages from T2 Biosystems in an amount to be proven at trial, but not less than a total of \$175,000.00.

COUNT TWO – QUANTUM MERUIT

- 44. VUMC reaffirms and realleges the foregoing paragraphs as if set forth fully herein.
- 45. Pleading in the alternative, and to the extent that the Court finds that there is no existing and enforceable contract between the parties for the entire amount due, VUMC is still entitled to the reasonable value of the performance of the Study activities provided to T2 Biosystems.
- 46. VUMC performed and completed Milestone Four and Milestone Five for the benefit of T2 Biosystems and the Study.
- 47. T2 Biosystems reasonably understood that VUMC expected payment for the performance and completion of Milestone Four and Milestone Five provided to the Study.
- 48. It would be unjust for T2 Biosystems to retain the value of the performance and completion of Milestone Four and Milestone Five of the Study provided by VUMC without payment to VUMC.
- 49. T2 Biosystems received and have had the benefit of the completion of Milestone Four and Milestone Five, which constitute value added to the Study.
- 50. VUMC has been damaged and T2 Biosystems unjustly enriched by T2 Biosystems' failure to pay VUMC for the completion of Milestone Four and Milestone Five provided to the Study.
- 51. VUMC is entitled to recover the reasonable value of the performance and completion of Milestone Four and Milestone Five provided to T2 Biosystems on the Study.

PRAYER FOR RELIEF

WHEREFORE, VUMC prays for the following relief:

1. An award of compensatory damages for the principal balance in an amount to be proven at trial, but not less than \$175,000.00;

- 2. An award of pre- and post-judgment interest as permitted by law; and
- 3. For all such other and further relief to which VUMC may be entitled as a matter of law or equity.

Respectfully submitted, this 24th day of April 2025.

BUTLER SNOW LLP

By: s/ Daniel W. Van Horn

DANIEL W. VAN HORN (18940)

CARA BAER (23483)

KATHERINE M. KUCHENBECKER (41377)

6075 Poplar Ave., Ste. 500

Memphis, TN 38119

(901) 680-7331

(901) 680-7201 (fax)

Danny.VanHorn@ButlerSnow.com

Cara.Baer@ButlerSnow.com

Katherine.Kuchenbecker@ButlerSnow.com

92544470.v1